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MAY - 8 2009

510(k) Summary of Safety and Effectiveness

SIEMENS Medical Solutions USA, Inc
syngo® RT Therapist Connect Workspace

Submitted By Siemens Medical Solutions USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
Concord, CA 94520

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Date Prepared March 11, 2009

Proprietary Name syngo® RT Therapist Connect

Common Name(s) (Accessory To) Medical Charged-Particle Radiation Therapy System

Classification Name(s) 21 CFR, Part 892.5050 (90IYE)

Predicate Device The syngo® RT Therapist Connect is substantially equivalent to the following devices:

Product	510(k)	Clearance Date
ARTISTE™ Solution (aka ARTISTE MV) with the syngo® RT Therapist workspace	K072485	December 27, 2007
ONCOR™ Expression with COHERENCE™ RT Therapist workspace	K060226	March 15, 2006
PreScision™ Option	K082775	February 19, 2009

Description Summary

Within the submission the following internal naming conventions are used:

Market Name	Internal naming convention
ARTISTE™	ARTISTE™ linear accelerator and ACCEL release 4+
Bay Bridge	Internal project name for the <i>syngo</i> ® Therapist Connect Workspace.
ONCOR™ Expression	ONCOR™ linear accelerator and ACCEL release 2+
PRIMUS™	PRIMUS™ linear accelerator and ACCEL release 2+
PRIMEVIEW™	Siemens proprietary verify and record system. The <i>syngo</i> ® based PRIMEVIEW is hosted on the COHERENCE™ and the re-branded <i>syngo</i> ® Therapist Workspace. The <i>syngo</i> base version is marketed as PRIMEVIEW3i and is used on the PRIMUS™ linear accelerator systems.
COHERENCE™ Therapist Workspace	RTT Workspace contains the SIEMENS proprietary verify and record system as well as access to the Oncology Information System and directly connects to the LINAC control console.
<i>syngo</i> ® RT Therapist Workspace and <i>syngo</i> ® RT Therapist Express™	RTT Workspace contains the SIEMENS proprietary verify and record system as well as access to the Oncology Information System and directly connects to the LINAC control console on the ARTISTE™ linear accelerator system.
<i>syngo</i> ® Therapist Connect Workspace	The <i>syngo</i> ® Therapist Connect Workspace does NOT contain the PRIMEVIEW verify and record application. The Third Party OIS system containing a verify and record application connects to the <i>syngo</i> ® Therapist Connect Workspace via a validated DICOM interface. The <i>syngo</i> ® Therapist Connect Workspace directly connects to the LINAC control console on the ARTISTE™ linear accelerator system.
<i>syngo</i> ® Suite for Oncology Workspaces	<i>Syngo</i> based workstation, re-branded COHERENCE workspaces.
<i>syngo</i> ®	Siemens proprietary software architecture and hosting SIEMENS software applications organized by task cards on a dedicated workstation.

For further definitions of the terms used in this submission, refer to the Glossary.

Technological Characteristics:

The *syngo*® Therapist Connect Workspace is an optional feature to the existing SIEMENS branded ARTISTE™ and ONCOR™ family of medical linear accelerator devices [LINAC]. The basic design, safety features and function of the LINAC control console and the linear accelerator treatment delivery, dosimetry, treatment recording and portal imaging subsystems remain unchanged.

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The *syngo*® Therapist Connect Workspace differs from the predicate COHERENCE and *syngo*® Therapist Workspaces in that it does not contain a Oncology Information System (OIS) or Verify and Record (V&R) application such as PRIMEVIEW. These functions are located on the Third Party OIS system. The *syngo*® Therapist Connect Workspace receives the treatment plan from a Third Party OIS system or Third Party Treatment Planning System (TPS), supports the final review of the treatment parameters and enables the Radiation Therapist to initiate the delivery of the treatment prescription.

Upon completion of the treatment prescription, a report is submitted to the Third Party OIS or TPS system in the form of a DICOM RT Structured Report. All other features such as patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording that are supported by the predicate COHERENCE and *syngo*® Therapist Workspaces remain unchanged.

R_x Required: The Linear Accelerator device and its accessories are intended to be used by trained medical professionals under the supervision and direction of a therapeutic radiologist.

General Safety and Effectiveness:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software development, verification of requirements and validation testing. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Intended Use:

The intended use of the SIEMENS branded ARTISTE™, ONCORT™ and PRIMUS™ family of linear accelerator systems is to deliver X-Ray photon and electron radiation for the therapeutic treatment of cancer.

The *syngo*® Suite for Oncology Workspaces:

The *syngo*® workspaces includes a number of *syngo*® based software applications whose indication for use include the viewing, processing, filming, and archiving of medical images. The workspaces also permit patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.

The *syngo*® RT Therapist Connect Workspace is an additional option when third party OIS, Treatment Planning Systems and/or PACS devices are intended to be used in conjunction

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with the Siemens branded Linear Accelerator system. The *syngo*® RT Therapist Connect Workspace is a software application that permits patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording. The *syngo*® RT Therapist Connect Workspace can be interfaced with third party devices conforming to the DICOM® Standard.

The addition of the *syngo*® RT Therapist Connect Workspace does not change the intended use of the Siemens branded Linear Accelerator System.

Verification and Validation Testing

Verification and Validation testing was performed to evaluate the performance and functionality of the *syngo*® RT Therapist Connect workspace software. This testing included software unit-level test, integration and system-level tests. The results demonstrate that the device satisfies all performance and functional requirements as stated in the Product Requirement Specifications.

Summary:

In summary, it is SIEMENS' belief that the *syngo*® RT Therapist Connect workspace option does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY - 8 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Christine Dunbar
Senior Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
4040 Nelson Avenue
CONCORD CA 94520

Re: K090683

Trade/Device Name: syngo[®] RT Therapist Connect Workplace
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: April 9, 2009
Received: April 10, 2009

Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

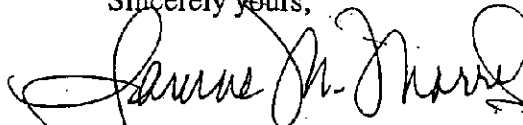
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number:

K090683

Device Name:

syngo® RT Therapist Connect Workspace

Indications for Use:

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The syngo® Suite for Oncology Workspaces:

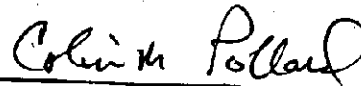
The syngo® workspaces includes a number of syngo® based software applications whose indication for use include the viewing, processing, filming, and archiving of medical images. The workspaces also permit patient data management, patient selection/setup, patient positioning verification, treatment planning, treatment delivery/verification, and treatment recording.

The syngo® RT Therapist Connect Workspace:

The syngo® RT Therapist Connect Workspace contains software applications that permits patient selection/setup, patient positioning verification, treatment delivery/verification, and treatment recording. The syngo® RT Therapist Connect Workspace is an option when third party OIS, Treatment Planning Systems and/or PACS devices conforming to the DICOM® Standard are intended to be used in conjunction with the Siemens branded Linear Accelerator system.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K090683

Prescription Use ☒

AND/ OR

Over-The-Counter Use ☐

(Part 21 CFR 801 Subpart D)

(Part 21 CFR 807 Subpart C)

Siemens Medical Solutions USA, Inc.

Oncology Care Systems Group

syngo® RT Therapist Connect 510(k) Submission

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